

DOCKET FILE COPY ORIGINAL

Before the  
FEDERAL COMMUNICATIONS COMMISSION  
Washington, D.C. 20554

OCT 18 1999

FEDERAL COMMUNICATIONS COMMISSION  
OFFICE OF THE SECRETARY

In the Matter of )  
 )  
Amendment of Parts 2 and 95 of ) ET Docket No. 99-255  
the Commission's Rules to Create a )  
Wireless Medical Telemetry Service )

**REPLY COMMENTS OF THE DATASCOPE CORP.**

The Datascope Corp. ("Datascope"), pursuant to Section 1.415 of the Commission's Rules, hereby files its reply to the initial comments filed by other parties on the Notice of Proposed Rulemaking in the above-captioned proceeding.<sup>1</sup>

It is Datascope's position that:

- Grandfathering should be allowed with continued use of current unlicensed and licensed frequencies for existing and new product,
- Governing technical standards must be agreed upon by device manufacturers prior to rule implementation, to avoid interference with medical devices, and
- The proposed near term medical telemetry bandwidth of 6 MHz is inadequate to meet even current needs.

Datascope Corp. manufactures and markets a broad line of physiological monitors designed to provide for patient safety and management of patient care. The monitors are capable of continuous and simultaneous

---

<sup>1</sup> *Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service*, ET Docket No. 99-255, Notice of Proposed Rulemaking, FCC 99-182 (rel. July 16, 1999) ("NPRM"). For the sake of brevity, Datascope will cite initial comments by the name of the commenting party, the relevant page number(s), and when it was dated, for example "Datascope at 9-10, dated September 15, 1999."

0+4

measurement of many different vital signs used in operating rooms, emergency rooms, critical care units, post-anesthesia care units, intensive care units, labor and delivery rooms and magnetic resonance imaging, or MRI units.

Datascope was one of the first companies to introduce (and is still a major player in) medical telemetry monitoring. Medical telemetry is one of the fastest growing market segments outside of home care in the United States.

## **I. GRANDFATHERING**

The Commission should clarify the language used in the following statement: “all medical telemetry equipment authorized must operate in the new frequency bands.”<sup>2</sup> This language, which probably is unintended, may inadvertently outlaw medical telemetry in currently used licensed and unlicensed bands. Consequently, lawfully manufactured and installed telemetry devices, based on the NPRM language, could be required to be withdrawn from the market.

The proposed framework would provide a windfall to medical device manufacturers in that all new wireless medical equipment would have to be purchased, while creating a financial disaster to health care facilities and, ultimately, health care consumers who would have to bear the financial burden. This could constitute an unconstitutional governmental taking of property without compensation. To avoid these problems, the Commission should perpetually grandfather present allocated spectrum for medical devices and/or consider

---

<sup>2</sup> NPRM at ¶ 41, released July 16, 1999; Symbol Technologies at 2, dated September 16, 1999.

economic reimbursements in order to facilitate the relocation of the medical telemetry community to the proposed band(s).<sup>3</sup>

Furthermore, the Commission should allow the marketplace and not regulatory mandates to drive the market for future wireless telemetry devices. The user should still have the ability to choose and operate both present and new devices that use extremely reliable communications. Moreover, if the users determine that they are subjected to objectionable interference within the proposed band(s), the manufacturers should have an option to offer the health care facility an alternative frequency in which to operate. Alternative frequencies available to health care facilities are necessary because:

- (A) The proposed near term medical telemetry bandwidth of 6 MHz is inadequate to meet even current needs;
- (B) Governing technical standards must be agreed upon by device manufacturers prior to rule implementation, to avoid interference with medical devices; and
- (C) The proposed band is restricted due to radio astronomy "keep out areas" and use of channels 36 and 38 in other locations.

In the event the FCC does not provide the full grandfathering relief for present medical devices requested by Datascope, the Commission should adopt, at a minimum, a framework similar to its approach for Emergency Medical Radio Service ("EMRS") providers.<sup>4</sup> In the EMRS Order, the Commission specified

---

<sup>3</sup> LMCC at 7, dated September 16, 1999.

<sup>4</sup> *Amendment of Part 90 of the Commission's Rules to Create the Emergency Medical Radio Service*, 8 FCC Rcd 1454 (1993) ("EMRS Order").

criteria for grandfathering EMRS providers through permanent waiver requests, even though the Commission relocated EMRS to a different spectrum band.<sup>5</sup>

In the alternative, if full grandfathering relief is rejected, the Commission should consider the American Hospital Association (“AHA”) comments on adopting a five-year transition period, commencing with the allocation of the new telemetry spectrum.<sup>6</sup> We fully reject the position of Motorola, Land Mobile Communications Council (“LMCC”), and others that request the FCC to maintain its position that, beginning two years from the effective date of final rules in this proceeding, all medical telemetry equipment authorized must operate in the new frequency bands.<sup>7</sup>

The basis of Motorola’s argument is that “multiple component vendors are available with off-the-shelf parts that could be used to develop new devices for use in this band quickly. In fact, AHA representatives confirmed that product

---

<sup>5</sup> Criteria for granting a permanent waiver include (1) demonstrating that adequate spectrum exists for EMS transmissions in its area of operation; or (2) the relocating of its medical paging system would disserve the public interest because there is no reasonable alternative channel for relocating the existing system; or (3) relocation would cause significant disruption of public safety communications. *Id.* at ¶ 25. EMRS providers such as Kaiser Foundation Hospitals obtained permanent waivers from the relocation requirements specified in the EMRS Order. *See, e.g., Kaiser Foundation Hospitals and Kaiser Foundation Health Plans, Inc. Petition for Permanent Waiver to Grandfather Special Emergency Radio Service Paging Facilities on 453.025 MHz in the Southern California Metropolitan Area*, 13 FCC Rcd 5294 (1998).

<sup>6</sup> AHA at 22, dated September 16, 1999.

<sup>7</sup> Motorola at 3-7, dated September 16, 1999; LMCC at 6-7, dated September 16, 1999.

currently exists in the 608-614 MHz band, indicating that there should be no time delay required for product development unless it is for spectrum allocated for future requirements.”<sup>8</sup> However, these AHA task force committee members prematurely developed a product without knowing, or agreeing to, technical standards, which may cause inefficient, and potentially unsafe or inefficacious use of the bands to the potential detriment to the other device manufacturers and health care facilities. Additionally, manufacturers that invested significant resources in maintaining or developing product cannot be reasonably expected to abandon their present efforts, and change course towards band(s) having no defined standards.

## **II. TECHNICAL STANDARDS ARE NECESSARY**

We have two major concerns regarding technical standards for the proposed medical telemetry band. First, the band under discussion, 608-614 MHz, is insufficient to meet even the current needs of the medical telemetry market.<sup>9</sup> Second, the lack of specific and governing technical standards for operating within the proposed band(s) for Wireless Medical Telemetry Service ("WMTS") may spawn interference and lead to inefficient, and potentially unsafe and inefficacious use of the band(s).

Without standardization, a manufacturer's radio might not be designed to tune to available frequencies and spectral slots could go unused. Excessive spurious sideband levels on a synthesized local oscillator, when

---

<sup>8</sup> Motorola at 4, dated September 16, 1999.

<sup>9</sup> AHA at iii, dated September 16, 1999.

unintentionally radiated, could jam weak signals. Poor synthesizer noise floor performance from a number of mobile transceivers could raise the ambient noise floor over an entire health care facility and could monopolize the entire spectrum within one facility and therefore restrict systems and/or users from being introduced into that facility. Further, interference could result in patient drop out, data loss, or misidentification or non-identification of serious health events.<sup>10</sup>

Technical standards, at a minimum, insure that best use is made of the allocated spectrum by limiting the interference caused by co-located users in the same bands and in adjacent bands. Standards also permit optimal design of wireless transceivers, both with respect to equipment cost and performance.

We agree with the Final Analysis Communication Services' comments that the Commission should require, after a thorough investigation, the WMTS to meet spectral efficiency design standards and to investigate the possibility of different operational schemes.<sup>11</sup> This assertion is also in accord with GE Marquette's comments, which note that:

[D]ifferent medical telemetry manufacturers will likely utilize different channelization or spread spectrum schemes for channel 37 telemetry

---

<sup>10</sup> For example, the U.S. distributor, Fukuda Denshi America Corp., reported that a patient died while connected to a Fukuda Denshi Telemetry System. The report said that a signal from another transmitter overpowered the signal from the patient's transmitter and was recorded and displayed at the central station. The signal detected and displayed was interpreted as "normal." No alarms were sounded. See United States, Food and Drug Administration (FDA). Center for Devices and Radiological Health, Manufacturer and User Facility Device Experience (MAUDE) Database [online], Rockville (MD): FDA; 22-Jul-1998.

<sup>11</sup> Final Analysis, at 37-38, dated September 16, 1999.

devices. The use of different modulation schemes and/or incompatible communications protocols may make the coexistence of medical telemetry devices of different suppliers impossible at a given location.<sup>12</sup>

Without a clearly defined technical standard or channelization scheme, which has been subject to objective and fair review, comment, re-draft and ratification, companies cannot begin the process of developing new technology which will perform efficiently and safely in the proposed band(s). Further, quick ratification and implementation, without the proper standards governing the implementation in place, will result in premature release of technology by companies rushing to "catch-up." This may create safety issues that will present more frequent patient safety hazards than exist under current wireless operating schemes. In sum, we know that everyone is striving to improve patient safety by minimizing interference but this cannot be achieved unless we have agreed upon technical standards governing the use of the limited band(s).

### **III. PROPOSED ALLOCATION OF AT LEAST 14 MHZ OF SPECTRUM**

Channel 37 (608-614 MHz) has been positioned as the obvious initial choice for health care facilities by the AHA task force.<sup>13</sup> Consequently, the number of patients per location capable of being monitored at a single facility using 608-614 MHz will be limited. According to the AHA, a single facility can monitor less than

---

<sup>12</sup> GE Marquette Medical Systems, Inc. ("GE Marquette"), at 8, dated September 16, 1999.

<sup>13</sup> GE Marquette, at 6, dated September 16, 1999.

600 patients based on the current proposed 6 MHz of spectrum. In addition, AHA estimates that within ten years a medium-to-large hospital will require an average operating capability of 1000 wireless medical devices.<sup>14</sup> This goal does not appear achievable within the proposed allocation.

In addition, the 608-614 MHz band presents serious limitations, as noted by GE Marquette and AHA. As specified in proposed section 95.1119 of the Commission's Rules, this band cannot be used in the vicinity of a number of radio astronomy observatories and in areas where broadcasters operate TV channels 36 or 38.<sup>15</sup> Consequently, health-care facilities in proximate areas could be precluded or adversely affected.

Furthermore, the assumption of spectral efficiency of 0.8 bits per second per Hertz is not achievable given current medical telemetry device technology, nor is it readily apparent that this efficiency is achievable within the time frames specified in this proposed ruling. Therefore, AHA's original assumption that 6 MHz of bandwidth would be sufficient to meet near-term health-care facility needs for WMTS, is without technical merit.

#### **IV. CONCLUSION**

Implementing the proposed medical telemetry band without well-defined standards may only lead to preservation of the shortcomings of the present

---


<sup>14</sup> AHA, at 4, dated September 16, 1999.

<sup>15</sup> GE Marquette Medical Systems, Inc., at 6, dated September 16, 1999; AHA, at iii, dated September 16, 1999.

band, as opposed to realizing the objective of a primary medical band. In addition, we strongly advocate continued availability of the presently utilized bands as an alternative to compensate for radio astronomy "keep out areas," as well as unanticipated events.

Respectfully submitted,

DATASCOPE CORP.

  
\_\_\_\_\_  
J. Gary Mohr by MCF  
Director of Legal Affairs  
Datascope Corp.  
14 Philips Parkway  
Montvale, NJ 07645

Dated: October 18, 1999